UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,987	10/01/2001	Andrew D. Murdin	032931-0253	7970

7590 10/27/2005

Bernhard D Saxe
Foley & Lardner
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,987	MURDIN ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004 and 18 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,20-38 and 79-83* is/are pending in the application.

4a) Of the above claim(s) *20-35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,36,38 and 79-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *20-35 and 37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *10/13/04 decision on petition*.

Response to Amendment

1. Applicant's amendment filed on 4/7/04 is acknowledged.

2. The response to the renewed petition for reconsideration of Restriction Requirement (11 March 2004) has been mailed to the applicant on 10/13/04. However, the examiner is enclosing the same to this office action as requested by the attorney of record.

Status of claims

3. Claims 1-4, 7-16, 25, 38, 79 and 80 have been amended in the amendment filed on 4/7/04.

Claims 18-19, 39-78 have been canceled.

New claims 81-83 have been entered.

Newly added claims 81-83 are drawn to nucleic acid and therefore, added to the elected invention.

Claims 1-17, 20-38, 79-83 are pending.

Claims 1-17, 36, 38, 79 and 80-83 are under prosecution with respect to DNA comprising SEQ.ID.NO: 1 and DNA encoding the SEQ ID NO: 14. Applicant is advised to amend claims, for example: 36 and 38 to restrict to the elected invention isolated nucleic acid. Claim 25 depends from a non-elected claim 21 and therefore, is withdrawn from the elected invention.

In view of the petition decision (10/13/04), claims 20-35, 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Information Disclosure Statement

4. Information Disclosure Statement filed on 7/18/05 is acknowledged and a signed copy is attached to this Office action.

Claim Rejection - 35 U.S.C. 102 moot

5. In view of cancellation of claims 18 and 19, the rejection under 35 U.S.C. 102(b) is moot.

35 U.S.C. 112 written description rejection maintained

6. The rejection of claims 1-17, 36 (a-d), 38(a-b), and 79-83 under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained as set forth in the previous office action.

The specification only describes a polynucleotide sequence of SEQ ID NO: 1. The specification describes as part of the invention-isolated polynucleotide encoding the polypeptide of SEQ ID NO: 14 (CPN 100686 RY 54), which is a "putative 98kDouter membrane protein (see pages 8-10). However, broadly claimed nucleic acid sequence which encodes a polypeptide SEQ.ID.NO: 14 variants/fragments, a nucleic acid comprising 38, 100 consecutive nucleic acids, a nucleic acid sequence encoding an immunogenic fragments of 50 or 12 consecutive amino acids and a method of preventing infection using such nucleic acid is not set forth in this specification. Applicants also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides by use of language in which a specified percent of amino acids can be changed. As depending from these are the vectors, host cells, vaccines, diagnostics and methods of producing the polypeptide. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polynucleotide sequence consisting of SEQ ID NO: 1 which corresponds to the polynucleic acid sequence encoding the Chlamydia pneumoniae protein which comprises SEQ ID N0: 14. Thus, an isolated polynucleotide sequence comprising of SEQ ID NO: 1 meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The claimed properties of the putative 98 kD protein can only be determined empirically by actually making every nucleic acid that encodes the recited fragments/variants and testing each to determine whether it encodes a protein having the particularly disclosed properties of an 98kDprotein. As noted in the Guidelines at Section I.A (2) there is no written description support for fragments/variants of SEQ.ID.NO: 14 or 1, vaccine vectors comprising said sequences,

pharmaceutical composition and a method of preventing or treating Chlamydial infection as claimed.

Applicants specification proposes the converse, yet still does not meet the requirements for an adequate written description of the claimed invention. Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicants invention as a 98kDprotein as disclosed. The 98kD outer membrane protein is uncharacterized by this specification and is not asserted to belong to any known family of proteins. The protein has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence which encodes it. There must be some nexus between the structure of a gene sequence and the structure of the protein encoded, and the function of that encoded protein. However, similar function cannot be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. Applicants have not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of a 98kDouter membrane protein as disclosed. While it is true that, due to the nature of codon degeneracy, applicant may take a reference sequence and modify that sequence to be a different nucleic acid sequence, yet still have that nucleic acid encode the same putative 98 kD protein. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number 98kDpolypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide comprising SEQ ID NO: 1 and an isolated polynucleotide comprising of a nucleotide sequence encoding SEQ ID NO: 14, fragments thereof and associated, vectors, vaccines, fusions etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Applicant continues to traverse the rejection. However, applicant's arguments 4/7/04 have been fully considered but they are not deemed to be persuasive.

Applicant states that the limitation 75% identity has been deleted from the claims and now the claims recite only fragments of elected sequences and such fragments have been disclosed in the specification and therefore, the rejection should be withdrawn.

The examiner disagrees with the applicant because the specification does not disclose fragments as claimed. The examiner understands that the specification teaches an isolated

polynucleic acid comprising the e nucleic acid SEQ.ID.NO: 1 which encodes the polypeptide as set forth in SEQ.ID.NO: 14 and therefore applicants are enabled for said isolated polynucleic acid and polypeptide. However, applicant is claiming an isolated polynucleic acid comprising nucleic acid sequence which encodes **a** polypeptide **comprising** immunogenic fragments of 50, 38 or 12 consecutive amino acid from SEQ.ID.NO: 14. Recitation of open language " comprising " in the claims does not limit to the fragments of SEQ.ID.NO: 14 but reads on fragments of SEQ.ID.NO: 14 plus other unknown and unlimited amino acids and are not supported by the present specification, pages 45-47.

Similarly, an isolated nucleic acid molecule comprising at least 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1 is not limited to an isolated nucleic acid molecule consisting of at least 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1 but reads on isolated nucleic acid comprising 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1 plus other unknown and unlimited nucleic acids and is not disclosed by the specification having specific and substantial function for the claimed fragments. Therefore, the rejection is proper and maintained.

35 U.S.C. 112 scope rejection maintained

7. The rejection of claims 1-17, 36 (a-d) 38 (a-b), 79- 83 under 35 U.5.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14, isolated vector comprising said nucleic acid, isolated host cell comprising said vector, and an immunogenic composition comprising an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14, the specification does not reasonably provide

enablement for an nucleic acid comprising a nucleic acid molecule encoding fragments of SEQ.ID.NO: 14 or a nucleic acid molecule comprising fragments of SEQ.ID.NO: 1 , or vaccine vector comprising an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1 and fragments, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14 and fragments or Pharmaceutical composition comprising an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1 and fragments, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14 and fragments , a method for preventing and treating using said composition of is maintained as set forth in the previous Office action.

The nature of the disclosed invention is preparing recombinant polypeptide from *C.pneumoniae*. The state of the art prior art in *C.pneumoniae* is devoid of making or using recombinant fragments as claimed. Moreover, protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid sequences (i.e. fragments) for different aspects of biological activity cannot be predicted a priori and must be determined empirically on a case-by-case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page1-6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological-activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3): 1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. Proteins with replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition. For example, Jobling et al. (Mol. Microbiol. 1991, 5(7): 1755-67 teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produces proteins that differ in native conformation, immunological recognition, binding and toxicity, thus exemplifying the importance of structural components to both biological function and immunological recognition. Thus, it is apparent that change in a peptide can lead to loss of binding property of that peptide.

The specification provides no working examples demonstrating (i.e., guidance) enablement for an isolated nucleic acid encoding polypeptide variants/fragment of SEQ.ID.NO: 14 or variants/ fragments of SEQ.ID.NO: 14 must be considered highly unpredictable, requiring a specific demonstration of efficacy on a case-by-case basis. Thus, the specification fails to provide an enabling disclosure for using variants/ fragments of SEQ.ID.NO: 14 or isolated nucleic acid SEQ.ID.NO: 1 because it fails to provide guidance how a variants/ fragments of

SEQ.ID.NO: 14 or fragments of SEQ.ID.NO: 1 are useful in diagnosing *C.pneumoniae* infection The specification provides no disclosure how a variants/ fragments of SEQ.ID.NO: 14 or SEQ.ID.NO: 1 may be used as a target for *Chlamydia* infection because it fails to provide guidance whether this variants/ fragments of SEQ.ID.NO: 14 or SEQ.ID.NO: 1 has the ability to bind to *C.pneumoniae* patient's sera obtained from various clinical samples. Therefore, the skilled artisan would not be able to use such broadly claimed variants/ fragments of SEQ.ID.NO: 14 or SEQ.ID.NO: 1

With respect to claimed composition as a vaccine composition or a pharmaceutical composition, the specification does not provide how would an artisan have used the vaccine vector comprising an isolated nucleic acid molecule comprising the nucleic acid sequence as set forth in SEQ ID NO: 1, an isolated nucleic acid molecule encoding the amino acid sequence as set forth in SEQ.ID.NO: 14, the protein and its variants to treat or prevent the infection against *Chlamydia* (including infection caused by C.pneumoniae or C.trachomatis). Furthermore, the patient's sera have not yet been shown to identify the claimed protein or its fragments in an *in vitro* assay. The specifications does not ensure that the protein or its variants would be able to successfully generate a protective immune response to treat or prevent an infection because the state of the art suggests that the protective immune response to infection with *Chlamydia* is associated with antibody reactivity to species specific, serovar specific and serogroup specific determinants on the major outer membrane proteins (see Allen et al, Journal of Immunology 1991, 147; 674-679 and Batteiger et al 1996, Infection and Immunity , 64; 2839 - 2841). Murdin et al (J. Infectious Diseases, 2000, 181, Suppl. 3:S552-S557) teaches that although considerable progress toward developing a C. pneumoniae vaccine has been made in the last 1-2 years, a true candidate vaccine does not yet exist (p. 5554). The development of a candidate vaccine requires the determination of both protective antigens and a safe, effective, formulation of those antigens." (p. S554). Murdin et al teaches that antigen formulation remains an area in which much information is still needed, including what constitutes a protective immune response to C. pneumoniae in humans, how to express recombinant antigen and how to formulate them to elicit a protective response in humans (see page 554). Therefore, the protective role of antibodies to claimed nucleic acid encoding polypeptide SEQ.ID.NO: 14 or isolated nucleic acid SEQ.ID.NO: 1 appears to be critical for protection and the specification fails to disclose such studies and is yet to be studied. Further, immune response generated by claimed DNA a, would be able to treat any and all Chlamydia infections as claimed are left for experimentation. Further, the specification provides no working examples demonstrating (i.e., guidance) enablement for any *in vivo* use *of* the claimed vaccine vectors or fragments/ variants thereof. However, it is unclear whether this approach is feasible in the treatment of Chlamydial infections using the claimed nucleic acid encoding SEQ.ID.NO: 14 or isolated nucleic acid SEQ.ID.NO: 1 has not been shown to treat even an ongoing Chlamydia infection. Thus, the claimed composition for the treatment or prevention of Chlamydial infection (including infection caused by C.pneumoniae or C.trachomatis) must be considered highly unpredictable, requiring a specific demonstration of efficacy of the claimed protein in treating specific Chlamydia infection.

With respect to Claim 36, the specification does not provide an enabling disclosure for the treatment of Chlamydia in patients following direct administration of any and all nucleic acid constructs of the instant invention i.e., a method of treating or preventing Chlamydia infection. The specification does not provide guidance for the construction of nucleic acid vectors which are adenoviral vectors, retroviral vectors, or herpes virus vectors, or the kinds of promoters that are functional in retroviral vectors or plasmid based vectors. The specification also does not

provide guidance for the dosage, or the routes of delivery of any and all nucleic acid constructs to a patient wherein the level of expression of the encoded fusion protein results in a therapeutic effect on the patient's Chlamydial infection. At the time of filing, gene therapy of Chlamydia using the direct administration of DNA was considered to be highly unpredictable. Verma et al state that, "A [t] he Achilles heel of gene therapy is gene delivery and that, most of the approaches suffer from poor efficiency of delivery and transient expression of the gene (Verma et al, 1997, Nature, Vol. 389, page 239, column 3, paragraph # 2). Miller et al (The FASEB Journal 1995, 9: 190-199) concurs, stating that, a difficulties in getting genes transferred efficiently to target cells- and getting them expressed- remain a nagging problem for the entire field," and that, many problems must be solved before gene therapy will be useful.

The applicant's specification does not demonstrate a correlation between the level of antibody generated using the claimed compositions in a method of preventing or treating infection i.e., therapeutic effect on a patient suffering from Chlamydial infection. Further, the specification does not provide guidance as to the level of anti-idiotypic antibody necessary to delay infection, decrease existing bacterial infection, or prevent the spread of infection. Therefore, it is concluded that the specification as filed is not enabling for the claimed vaccine vectors, vaccine compositions, pharmaceutical composition and a method of treating or preventing infection as filed and an artisan would not have been able to practice the invention without undue experimentation.

Applicant's arguments filed on 4/7/04 have been fully considered but they are not deemed to be persuasive. First, Applicant states that the instant application is not concerned with the biological activity of the protein but rather the specification describes the claimed nucleic acid and polypeptides in terms of their utility as immunogenic compounds. Further, applicant argues that peptides with 6-15 amino acids generate an immune response and antibodies to such peptides are commercially available.

First, the examiner would like to clarify the issue of "biological activity "and " utility" because in applicant's concept peptide biological activity and utility as immunogenic compounds are different. It is very well know in the art of immunology making antibodies to peptides with 5-8 amino acids of a protein. However, the antibodies produced by such peptide should be able to recognize the full-length protein and thus the peptide is immunogenic and has the ability to bind to an antibody (property/function) and could be used as a diagnostic tool and thus has utility. Thus, an immunogenic compound i.e., fragment has utility with a specific function. Secondly, Applicant asserts that the limitation 75% identity has been deleted from the claims and now the claims recite fragments and therefore, the rejection should be withdrawn.

The examiner disagrees with the applicant because the specification does not disclose an isolated nucleic acid molecule comprising a nucleic acid molecule which encodes a polypeptide selected from an immunogenic fragment comprising 50 or 12 consecutive amino acid from SEQ.ID.NO: 14 plus other unknown and unlimited amino acids nucleic acids or an isolated nucleic acid molecule comprising a nucleic acid molecule at least a 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1 plus other unknown and unlimited nucleic acids, vaccine vector comprising said nucleic acid as discussed in the above written description

Finally, the examiner would like to point to the applicant, fragments as claimed are not shorter than SEQ.ID.NO: 14 because applicant is not claiming an isolated nucleic acid molecule consisting of (open language) a nucleic acid molecule which encodes the polypeptide selected from an immunogenic fragment consisting of 50 or 12 consecutive amino acid from SEQ.ID.NO: 14 or an isolated nucleic acid consisting of at least a 38 or 100 consecutive nucleic acids from SEQ.ID.NO: 1.

Therefore, the fragments as claimed are broader than the claimed SEQ.ID.NO: 14 or SEQ.ID.NO: 1.

Claim Rejection - 35 USC 102 maintained

8. The rejection of claims 1, 2, 8, 16, 38 (a) (b) and 79-81 under 35 U.S.C. 102(e) as being clearly anticipated by Griffais U.S.Patent 6, 559, 294 is maintained as set forth in the previous office action.

Griffais U.S.Patent 6, 559, 294 discloses a nucleic acid sequence SEQ.ID.NO: 1(see the sequence alignment with the claimed nucleic acid) from *C. pneumoniae* which encodes a polypeptide, immunogenic fragment comprising at least 50 consecutive amino acids, nucleic acid molecule comprising 38 consecutive nucleotides (see the sequence alignment) and is 98.3 % identical to SEQ ID NO: 14. Therefore, the prior art meets the limitations of claimed nucleic acid molecule. The prior art anticipated the claimed invention.

Please note that the examiner has clearly indicated that the examiner is unable to locate

the application 09/198,452 (U.S.Patent 6, 559, 294) in the previous Office action and the examiner is using the filing date of this application 11/23/1998 as 102 (e) date. However, the examiner now obtained the application 09/198,452. Upon review of the application the 102 (e) for the Griffais U.S.Patent 6, 559, 294 is **11/21/1997**.

The Declaration provided by Andrew Murdin under 37 CFR 1.132 filed 4/07/04 is acknowledged. The declaration shows that the applicant possessed these amino acid and nucleotide sequences, SEQ.ID.NO: 14 and SEQ.ID.NO: 1 prior to November 4, 1998. However, the disclosed prior art, Griffais U.S.Patent 6, 559, 294, 102(e) date is 11/21/1997. The Declaration does not overcome the rejection of record as applicant was not in possession of the claimed amino acid and nucleotide sequences, SEQ.ID.NO: 14 and SEQ.ID.NO: 1 prior to 11/21/1997 as required. Therefore, the Declaration provided by Murdin et al is insufficient to overcome the rejection of record.

Claim Rejections - 35 U.S. C. § 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claim 13 is rejected under 35 U.5.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague in reciting "additional polypeptide ". It is not clear what are the metes and bounds of additional polypeptide, which enhances the immune response to at least one polypeptide?

11. Claim 3 and claim 1 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hillier et al (Genome Research. Vol 6, no 9, pages 807-828. 1996.

Hillier et al (Genome Research. Vol 6, no 9, pages 807-828. 1996) disclose the nucleic acid sequence, which is 100 % complementary (i.e., antisense) to the nucleotides 370-388 of SEQ ID NO: 1 of the instant claim 3, which is within the scope of the presently claimed invention (See the attached sequence alignment) It is noted since claim 3 recites an isolated nucleic acid molecule comprising a nucleic acid sequence, which is anti-sense to the nucleic acid molecule of claim 1 and the specification disclosure does not define the anti-sense sequence length that corresponds to the nucleic acid sequence of claim 1, therefore the reference sequence anticipated the claimed nucleic acid molecule .

Remarks

12. No claims are allowed.

Conclusion

13. This application contains claims 20-35, 37 that are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

15. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,987	10/01/2001	Andrew D. Murdin	032931-0253	7970

7590 10/13/2004

Bernhard D Saxe
Foley & Lardner
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BERNHARD SAXE
FOLEY & LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON DC 2007-5109

In re Application of :
MURDIN et al :
Serial No. : 09/868,987 :
Filed : 23 December 1999 :
Attorney Docket No. : 03293/0253 :

Decision on Petition

This letter is in response to the Renewed Petition for Reconsideration of Restriction Requirement filed on 11 March 2004. The delay in acting upon this petition is regretted.

BACKGROUND

This application is filed as 35 USC 371 of the National Stage filing of PCT/CA99/01230, filed 23 December 1999, which claims priority to several provisional applications filed on 12/23/98 and 12/28/98.

On 27 July 2003, applicants have filed a petition to review the restriction requirement set forth by the examiner on 4 October 2002.

The petition was granted in-part on 13 January 2004. In the petition decision, the restriction requirement between DNA comprising SEQ ID NO: 1 and DNA encodes SEQ ID NO: 14 has been withdrawn. Claim 38, directed to a kit comprising DNA, protein or antibody has been rejoined to the product claims of group I, II and III respectively. The method of claim 37 has been divided in three groups IV, V and VI drawn to method of detecting using DNA, protein or antibody, respectively.

The resulting groups are summarized as follows:

Group I, claims 1-19, 25, 36, 38 (a), 79, 80-83, drawn to DNA, vector, host cell, kit and a method of expressing the DNA and a method of preventing infection by administering the DNA.

Group II, claims 20-24, 27-24, 36 and 38 (b), drawn to polypeptide and vaccine, and a method of preventing infection by administering a peptide.

Group III, claims 26, 35, and 38 (c) drawn to an antibody, and a method of preventing infection by administering an antibody.

Group IV, claim 37 (a) drawn to a method of detecting Chlamydia infection using nucleic acid.

Group V, claim 37 (b), drawn to a method of detecting Chlamydia infection using a peptide.

Group VI, claim 37 (c) drawn to a method of detecting Chlamydia infection using an antibody.

Group VII, claim 39, drawn to a method for inducing an immune response using a polypeptide.

On 11 March 2004, applicants filed a renewed petition for reconsideration of Restriction Requirement, a 37 CFR 1.131 Declaration by inventor Andrew Murdin, and amendment to claims 1-4, 7-17, 20-21, 25, 27-28. 33-38, 79-80, and added new claims 81-83.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and(2).

In addition to the categories provided for in 37 CF 1.475(b) (1-5) , unity of invention is explicitly provided for in the following context:

Claim 1: Protein X
Claim 2: DNA sequence encoding protein X.

wherein expression of the DNA sequence in a host results in the production of a protein, which is determined by the DNA sequence. The protein and the DNA sequence exhibit corresponding special technical features. Unity of invention between claims 1 and 2 is accepted.

See MPEP 1893.03(d) and Annex B, Part 2 of the PCT Administration Instructions, Example 17.

Unity of invention has to be considered in the first place only in relation to the independent claims in an international and not the dependent claims and (i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;
(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part 1 "Instructions Concerning Unity of Invention" MPEP AI-6 (Rev. 1. Feb. 2003).

DISCUSSION

The petition and application file history have been considered carefully. A summary of the prosecution history can be found in the decision concerning the first petition mailed on 13 January 2004.

The above-identified application is a national stage application submitted under 35 U.S.C. 371 to which "unity of invention", and not U.S. restriction practice is applicable. MPEP section 189.03(d).
The lack of unity between the groups I-VII and the technical feature linking groups I-II is at issue, especially between nucleic acid encoding the peptide of SEQ ID NO: 14 and the peptide of SEQ ID NO: 14 are at issue.

Representative claims of group I:

Amended Claim 1: An isolated nucleic acid molecule comprising a nucleic acid sequence which encodes a) SEQ ID NO: 14; b) an immunogenic fragment comprising at least 50 consecutive amino acids from SEQ ID NO: 14.
Claim 3: An isolated nucleic acid molecule comprising a nucleic acid sequence, which is anti-sense to the nucleic acid molecule of claim 1.

Representative claims of group II:
Amended Claim 21: An isolated polypeptide comprising an amino acid sequence selected from: a) SEQ ID NO: 14; and b) an immunogenic fragment comprising at least 12 consecutive amino acids from SEQ ID NO: 14.

It is noted that the independent claim 1 and 21 above, are drawn to a genus of nucleotides encoding a genus of polypeptides and not a single species of polypeptide and the genus of polynucleotides that encode it as in Example 17.

The polynucleotide of group I does not share a common structure or function or property with the polypeptide of group II. Further neither the nucleic acid molecule comprising a nucleic acid sequence which is anti-sense to the nucleic acid molecule of claim 1, nor the nucleic acid sequence which encodes an immunogenic fragment comprising at least 50 consecutive amino acids from SEQ ID NO: 14 are required to or could possibly encode the polypeptide comprising amino acid sequence of SEQ ID NO: 14, such that according to the PCT Administrative Instructions, Example 17 the inventions exhibit no corresponding special technical feature.

According to the PCT Rule 13.2, the special technical feature shall mean those technical features that define contribution which each of the claimed inventions, considered as whole makes over the prior art.

The technical feature of group I is considered as polynucleotide.
The technical feature of group II is considered as polypeptide.
The polynucleotide is made of nucleic acids, and the polypeptide is made of amino acids.
Thus, the polynucleotides of group I, and the polypeptides of group II are not linked by the same or corresponding technical feature as defined by PCT Rule 13.2.

In the present instance neither the polynucleotide of group I and nor the polypeptides of group II exhibit a corresponding special technical feature since Hillier et al (Genome Research. Vol 6, no. 9, pages 807-828. 1996) teaches the nucleic acid sequence, which is 100 % complementary (i.e., antisense) to the nucleotides 370-388 of SEQ ID NO: 1 of the instant claims, which is within the scope of the presently claimed invention. It is noted since claim 3 recites 'an isolated nucleic acid molecule comprising a nucleic acid sequence, which is anti-sense to the nucleic acid molecule of claim 1', and the specification disclosure does not define the antisense sequence length that corresponds to the nucleic acid sequence of claim 1, the reference sequence would anticipate the claimed nucleic acid molecule. See the attached sequence alignment.

Thus, the nucleic acid molecule of group I do not share a special technical feature with the polypeptides of group II.

The technical feature of group I, the nucleic acid molecule of claim 1, is not present in the groups II-III, and groups V-VII.
Because Hillier et al teach the nucleic acid of claim 3 (group I), the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence the unity of invention is lacking.

Upon reconsideration, the Finality of the office action, mailed on 28 June 2004 has been withdrawn as being premature. The application will be forwarded to the examiner for preparation of an action consistent to this petition decision.

DECISION

Applicant's renewed petition for reconsideration of Restriction requirement between groups I-VII under 37 CFR 1.144 is **DENIED** for the reasons set forth above.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

It is noted that the renewed petition for reconsideration of restriction requirement (filed on 11 March 2004) is signed by attorney Thuy H. Nguyen of address Smart & Biggar of Canada. However, no revocation of power of attorney has been found in this application. Thus the petition decision will be addressed to the Attorney of record with a copy to be mailed to Attorney Nguyen.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

Jasemine C. Chambers

Jasemine Chambers
Director, Technology Center 1600.

ADDRESS:

THUY H. NGUYEN
SMART & BIGGAR
900-55 METCALFE STREET
OTTAWA, ONTARIO
CANADA, KIP 5Y6